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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/644,252 | 08/20/2003 | Thomas Zdeblick | 4002-3378/PC242.38 | 6078 |

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| EXAMINER |
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WOO, JULIAN W

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| ART UNIT | PAPER NUMBER |
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3731

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|---------------------------------|--|
| Office Action Summary | Application No. 10/644,252 | Applicant(s) ZDEBLICK ET AL. | |
| | Examiner Julian W. Woo | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-25, 30, 32-37, 40-43 and 45-50 is/are rejected.
- 7) ☒ Claim(s) 26-29, 31, 38, 39, and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>8/20/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 19 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 6,645,206.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim a fusion device having an elongate body and external threads, where the body is at least partially formed of a porous biocompatible material.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 19, 30, 32, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirabayashi et al. (4,259,072). Hirabayashi et al. disclose, in figure 1 and in col 4, lines 10-49, a fusion device with a solid, elongate body (1), external threads (11) substantially along the length of the body, and a hollow interior, where the body is formed of a porous biocompatible material. Note: The introductory statement of intended use ("for facilitating arthodesis in a disc space between adjacent vertebrae") has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Hirabayashi et al., which is capable of being used as claimed if one desires to do so.

5. Claims 32, 33, 40, and 45-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuslich (5,591,235). Kuslich discloses, in figures 7 and 9 and in col. 5, lines 52-60, a fusion device having a solid, elongated body (80), a hollow interior, an opening (82) in communication with the hollow interior, a pair of oppositely opposed arcuate side walls, a pair of truncated side walls (86 and 88 or 84 and the flat opposite of 84), and bone growth inducing material ("bone graft"), where the body is formed of a porous, biocompatible material

6. Claims 40, 45, 49, and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Kim et al. (5,645,596). Kim et al. disclose, in figures 1 and 2 and in col. 4 lines 31-46, a fusion device with a solid, tapering, elongated body (10), a pair of

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oppositely disposed arcuate surfaces (12), and a pair of truncated side walls (11), where the body is formed of a porous biocompatible material.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 20-25 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirabayashi et al. in view of Kaplan (5,282,861). Hirabayashi et al. disclose the invention substantially as claimed, but do not disclose a porous biocompatible material that is a composite comprising an open-celled substrate having interconnected porosity and infiltrated with a metal, where the substrate is a carbonaceous material or carbon foam, where the metal is a group VB metal or tantalum, and where the material has a modulus of elasticity approximately equal to a modulus of elasticity of human bone. Kaplan teaches a composite comprising an open-celled substrate having interconnected porosity and infiltrated with a metal, where the

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substrate is a carbonaceous material or carbon foam, where the metal is a group VB metal or tantalum, and where the material has a modulus of elasticity approximately equal to a modulus of elasticity of human bone. It would have been obvious to one having ordinary skill in the art at the time the invention was made to apply a composite as taught by Kaplan in the invention of Hirabayashi et al. Such a material would produce a fusion device that has excellent tissue acceptance, provides a matrix for bone ingrowth, and has a formable structure that mimics bone.

9. Claims 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich in view of Kaplan. Kuslich discloses the invention substantially as claimed, but do not disclose a porous biocompatible material that is a composite comprising an open-celled substrate having interconnected porosity and infiltrated with a metal, where the substrate is a carbonaceous material, and where the metal is a group VB metal, Kaplan teaches a composite comprising an open-celled substrate having interconnected porosity and infiltrated with a metal, where the substrate is a carbonaceous material, and where the metal is a group VB metal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to apply a composite as taught by Kaplan in Kuslich's invention. Such a material would produce a fusion device that has excellent tissue acceptance, provides a matrix for bone ingrowth, and has a formable structure that mimics bone.

Allowable Subject Matter

10. Claims 26-29, 31, 38, 39, and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a fusion device having, inter alia, a solid, elongate body, external threads substantially along the length of the body, and a hollow interior, where the body is formed of a porous biocompatible material, where the external threads are circumferentially interrupted by a pair of oppositely disposed truncated side walls to define a pair of arcuate side walls, and where the body has a first diameter adjacent a first end and a larger second diameter adjacent an opposite second end.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

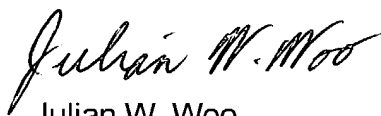
General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script that reads "Julian W. Woo".

Julian W. Woo
Primary Examiner

May 14, 2004